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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,593	11/29/2001	Seiji Sakano	KP8447DIV	2953

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/995,593	<b>Applicant(s)</b> SAKANO ET AL.	
	<b>Examiner</b> Prema M. Mertz	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 89-91 and 98-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 89-91, 98-100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. Claims 1-88, 92-97 have been canceled previously. Amended claims 89-91 (2/25/05) and new claims 98-100 are pending in the instant application and are under consideration by the Examiner.

2. Receipt of applicant's arguments and amendments filed on 2/25/2005 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 2/25/2005:

(i) the rejection of claims 89-91 under 35 U.S.C. § 112, second paragraph. However, this withdrawal is rendered moot in lieu of the new 35 U.S.C. § 112, second paragraph rejection over new claims 98-100.

4. Applicant's arguments filed on 2/25/05 have been fully considered but were persuasive in part. The issues remaining and new issues are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim rejections-35 USC § 112, first paragraph***

6. Claims 89-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained for reasons of record set forth at pages 2-3 of the previous Office action (8/30/04).

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Applicants argue that from Examples 10, 11, 12, in the specification, it can be concluded that differentiation suppression can be extrapolated or inferred. Applicants also argue that the colony assay in Example 10 correlates to the assays in the Gordon (1993) reference, at page 191 in the reference. However, contrary to Applicants' arguments, differentiation and proliferation are disparate processes and when proliferation is obtained, it cannot be extrapolated to indicate differentiation. It is unclear from the specification, Example 10, lines 3-4, whether the blood undifferentiated cells which are CD34 positive cells are "stem cells" because differentiation is obtained when stem cells differentiate (for example cancer cells are dedifferentiated cells). The passage recited from the Gordon reference, at page 191, is true about using clonogenic assays to obtain information about proliferation and differentiation. However, the issue here is that in the instant application only proliferation of colonies has been shown (see Figures 2A and 2B). The instant specification does not reveal any results regarding differentiation of the cells.

Applicants have provided Table I on page 8 of the arguments, however, it is unclear from Examples 10-12, whether the starting materials for the experiments were stem cells. In addition, all that has been demonstrated in these Examples is an increase in the number of colonies not in the differentiation of these cells. For example, in Figure 2A if the cells utilized in the assay are stem cells, and these control stem cells (in the absence of serrate-1 protein) show 10 differentiated cells and in the presence of serrate-1 the number of differentiated cells is suppressed, this result would indicate that serrate-1 suppresses differentiation in the stem cells. However, this is not a result or conclusion that can be obtained from the instant specification. The burden of demonstrating differentiation of the cells is on Applicants and Applicants have failed to demonstrate differentiation of blood precursor cells.

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***Claim Rejections - 35 USC § 112, second paragraph***

7. Claims 89-91, 98-100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 89-91 are rejected as vague and indefinite for reciting "blood precursor cells and hematopoietic stem cells". This recitation is redundant because "blood precursor cells" includes "hematopoietic stem cells".

Claims 98-100 are rejected as vague and indefinite because of several reasons. Firstly, the claims are vague and indefinite because they recite a method but fail to recite steps in the claimed method. Secondly, the claims fail to recite the result achieved by the method. Thirdly, the claims fail to recite in the preamble what is to be achieved by contacting the cells with serrate-1 peptide.

***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Prema Mertz*  
Prema Mertz Ph.D.  
Primary Examiner  
Art Unit 1646  
March 15, 2005